PATENT

Docket No. 2016-4000US5

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s)

Ralph M. Steinman, et al.

Group Art Unit: 1644

Serial No

09/073,596

Examiner: F. Pierre VanderVegt

Filed

May 6, 1998

For

METHOD FOR IN VITRO PROLIFERATION OF DENDRITIC CELL PRECURSORS

AND THEIR USE TO PRODUCE IMMUNOGENS

INFORMATION DISCLOSURE STATEMENT

ASSISTANT COMMISSIONER FOR PATENTS Washington, D.C. 20231

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§1.56, 1.97 and 1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application.

The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. [X] For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

Dechema Biotechnol. Conf. 4(Pt. A Lect. Dechema Annu. Meet. Biotech. 8th, 1990), pp. 181-184 – Abstract Only

- 2. [] For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.
- 3. [X] Any copy of the items listed on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in application Serial No. 458,230, filed June 2, 1995, now U.S. Patent Number 5,851,756, issued December 22, 1998.

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4. Copies of references not previously cited by or submitted to the Patent and Trademark Office in [X] application Serial No. 458,230, filed June 2, 1995, now U.S. Patent Number 5,851,756, issued December 22, 1998, are listed on Attachment A for the examiner's convenience. 5. [] No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with: [] 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application for filing date of the continued prosecution application filed on []37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in §1.491 in an international application; or [] 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office Action on the merits, whichever event occurred last. 6. [] No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below. 7. [X] A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action): A check in the amount of \$240.00 is enclosed in payment of the fee. [] [X] Charge the fee to Deposit Account No. 13-4500. Order No. 2016-4000US5. A DUPLICATE COPY OF THIS SHEET IS ATTACHED. 8. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by: a. [] one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and b. [] the attached petition requesting consideration of this Information Disclosure Statement; and the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below. 9. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with: 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue; b. [] 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the

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	instant application and is accompanies by the attached Petition To withdraw Application From Issue.	
c. []	The fee due under 37 C.F.R. §1.17(i)(1) is paid as set forth in paragraph 10 below.	
in a co	by certify that each item of information contained in the Information Disclosure Statement was cited ommunication from a foreign patent office in a counterpart foreign application not more than three is prior to the filing of this Information Disclosure Statement.	
[]	I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after make reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.	
11. [] A chec	ck in the amount of \$130.00 is enclosed in payment of the fee due under C.F.R. §1.17(i)(1).	
[]	Charge the fee due under C.F.R. §1.17(i)(1) to Deposit Account No. 13-4500. Order No. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.	
[]	The Assistant Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 13-4500. Order No A DUPLICATE COPY OF THIS SHEET IS ATTACHED.	
	Respectfully submitted,	
	MORGAN & FINNEGAN, L.L.P.	
Dated: October	16, 2000 By: Mind Donney De	
	Kenneth H. Sonnenfeld Registration Number 33,285	

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FORM: IDS.NY Rev. 05/26/98

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ATTACHMENT A

5,130,144	07/14/92	CIVIN
5,364,783	11/15/94	RULEY
5,851,756	12/22/98	STEINMAN
5,994,126	11/30/99	STEINMAN
028479	10/26/95	wo
020185	10/14/93	WO
013632	9/19/91	WO
0546787	6/16/93	EP

Abbas, et al, "Uptake & Processing of Extracellular Protein Antigens by Antigen-Presenting Cells," <u>W.B. Saunders Co.</u>, 1991 at 124-126.

Abbas, et al, "Cellular and Molecular Immunology, <u>W.B. Saunders Co.</u>, Philadelphia 1991, at 117.

Akagawa, et al., "IL-4 Stimulates the Generation of Dendritic Cells and Multinucleated Giant Cells From Human Monocytes," <u>Lymphokine and Cytokine Research</u>, 12(5):326 (1993).

Ardavin, et al., "Thymic Dendritic Cells and T Cells Develop Simultaneously in the Thymus from a Common Precursor Population," <u>Nature</u>, 362:761-763, Apr. 1993.

Austyn, et al., "Isolation And Characterization of Dendritic Cells From Mouse Heart And Kidney," <u>J. Immunol.</u>, 152:2401-2410 1994.

Austyn, J.M., "Lymphoid Dendritic Cells," Immunol., 62:161-170 1987.

Baker, et al., "Endocrine Diseases," <u>Basic & Clinical Immunol.</u>, 7^{th} Ed., Appleton & Lange, 1991.

Boon, "Tumor Antigens Recognized by Cytolytic T Lymphocytes: Present Perspectives For Specific Immuno Therapy," Int. J. Cancer, 54: 177-180, 1993.

Cohen et al, "Murine Epidermal Langerhans Cells and Splenic Dendritic Cells Present Tumor-Associated Antigens to Primed T Cells," <u>Eur. J. Immunol.</u>, 24: 315-319: 1994.

Coulie et al, "Genes Coding for Antigens Recognized on Human Tumors by Autologous Cytolytic T Lymphocytes," <u>Ann.NY.Acad.Sci.</u>, Vol. 690: pp. 113-119: 1993.

De Bruijn et al, "Mechanism of Induction of Primary Virus-Specific Cytotoxic T Lymphocyte Responses," <u>Eur. J. Immunol.</u>, 22: 3013-3020, 1992

Dechema Biotechnol. Conf. 4(Pt. A Lect. Dechema Annu. Meet. Biotech. 8th, 1990), pp. 181-184

Disis et al, "In Vitro Generation of Human Cytolystic T-Cells Specific for Peptides Derived from the Her-2/neu Protooncogene," <u>Canc.Res.</u>, 54: 1071-1076, 1994.

Dranoff et al, "Vaccination with Irradiated Tumor Cells Engineered to Secrete Murine Granulocyte-Macrophage Colony-Stimulating Factor Stimulators Potent, Specific, and Long-Lasting Anti-Tumor Immunity," <u>PNAS</u>, 90: 3539-3543, April 1993.

Eaves, "Peripheral Blood Stem Cells Reach New Heights," <u>Blood</u>, (1993) 82. No. 7, pp. 1957-1959.

Egner, et al., "The Phenotype of Freshly Isolated and Cultured Human Bone Marrow Allosstimulatory Cells: Possible Heterogeneity In Bone Marrow Dendritic Cell Populations," lmmunology, 85:611-620 1995.

Enami, et al., "Introduction of Site-Specific Mutations into the Genome of Influenza Virus," PNAS, 87/10:3802-3805 May 1990.

Ema, et al., "Colony Formation of Clone-Sorted Human Hematopoietic Progenitors," <u>Blood</u>, 75/10:1941-1946, May 15, 1990.

Enami, et al., "High-Efficiency Formation of Influenza Virus Transfectants," <u>J. Virol.</u>, 65/5:2711-2713 May 1991.

Flamand et al, "Vaccination with Tumor Antigen-Pulsed Dendritic Cells Induces in Vivo Resistance to a B Cell Lymphoma," <u>Adv. Exp. Med. Biol.</u>, 329: 611-615, 1993.

Flamand et al, "Murine Dendritic Cells Pulsed in Vitro with Tumor Antigen Induce Tumor Resistance in Vivo," <u>Eur. J. Immunol.</u>, 24: 605-610, 1994.

Fossum, "Lymph-Borne Dendritic Leucocytes do not Recirculate, but Enter the Lymph Node Paracortex to Become Interdigitating Cells," <u>Scand J. Immunol.</u>, 27:97-104 1988.

Freudenthal, Peter S., et al., "The Distinct Surface of Human Blood Dendritic Cells, As Observed After An Improved Isolation Method," <u>PNAS</u>, Oct. 1990, vol. 87, pp. 7698-7702.

Gaugler et al, "Human Gene Mage-3 Codes for an Antigen Recognized on a Melanoma by Autologous Cotolyit T Lymphocytes," <u>J. Exp. Med.</u>, 179: 921-930, 1994.

Gerdes. et al, "Cell Cycle Analysis of A Cell Proliferation-Associated Human Nuclear Antigen Defined by The Monoclonal Antibody KI-67," <u>J. Immunol.</u>, 133: 1710-1715, 1984.

Grabstein, et al., "Cloning of a T Cell Growth Factor that Interacts with the ß Chain of the Interleukin-2 Receptor," <u>Science</u>, 264:965-966, May 13, 1994.

Gaur, et al, "Amelioration of Autoimmune Encephalomyelitis by Byelin Basic Protein Synthetic Peptide-Induced Anergy," Science, 258: 1491-1494, 1992.

Ham, et al., "Cell Culture," <u>Methods in Enzymology</u>, Volume LVIII, pp 44-93, 1994.

Hosaka, et al., "Entry of Heat-Inactivated Influenza Virus and Induction of Target Susceptibility to Cytotoxic T Cell-Mediated Lysis," <u>Virus Res. Suppl.</u>, 1:56 1985.

Huang, et al, "Role of Bone Marrow-Derived Cells in Presenting MCH Class 1-Restricted Tumor Antigens," <u>Science</u>, 264: 961-965, 1994.

Inaba, et al, "Granulocytes, Macrophages and Dendritic Cells Arise From A Common Major Histocompatibility Complex Class II-Negative Progenitor In Mouse Bone Marrow," <u>Proc. Natl. Acad. Sci.</u>, 90: 3038-3042, 1993.

Jensen, P.E., "Protein Synthesis in Antigen Processing," <u>J.Immunol.</u>, 141: 2545-2550, 1988.

Jansen et al, "Inhibition of Human Formation by Interleukin-4," <u>J. Exp. Med.</u>, 170:577-582, 1989.

Kampgen, et al., "Class II Major Histocompatibility Complex Molecules of Murine Dendritic Cells: Synthesis, Sialylation of Invariant Chain, and Antigen Processing Capacity Are Downregulated Upon Culture," Proc. Natl. Acad. Sci., USA 88:3014-3018, 1991.

Kashihara, et al., "A Monoclonal Antibody Specifically Reacative to Human Langerhans Cells," J. Invest. Dermatol., 87/5:602-607, Nov. 1986.

Katz, et al., "Epidermal Langerhans Cells are Derived from Cells Originating in Bone Marrow," Nature, 282:324-326, 1979.

Knight, et al., "Role of Veiled Cells In Lymphocyte Activaton," <u>European Journal of Immunology</u>, Vol. 12, pp. 1057-1060, 1982.

Lanzavecchia, "Identifying Strategies for Immune Intervention," <u>Science</u>, (1993) 260: 937-944.

Larsen, et al., "Regulation of Immunostimulatory Function and Costimulatory Molecule (B7-1 and B7-2) Expression on Murine Dendritic Cells," <u>Am. Assoc. Immunologists</u>, 1994, pp. 5207-5219

Li, et al., "Priming with Recombinant Influenza Virus Followed by Administration of Recombinant Vaccine Virus Induces CD8+ T-Coil-Mediated Protective Immunity Against Malaria," PNAS, 90:5214-5218, Jun. 1993.

Li, et al., "Influenza A Virus Transfectants with Chimeric Hemagglutinins Containing Epitopes from Different Subtypes," <u>Journal of Virology</u>, 66/1:399-404, Jan. 1992.

Lu et al, "Propagation of Dendritic Cell Progenitors from Normal Mouse Liver Using Granulocyte/Macrophage Colony-Stimulating Factor and Their Maturational Development in the Presence of Type-1 Colligen," <u>J. Exp. Med.</u>, 179: 1823-1834, 1994.

Luytjes, et al., "Amplification, Expression and Packaging of a Foreign Gene by Influenza Virus," <u>Cell</u>, 59:1107-1113, Dec. 1989.

Macatonia, et al., "Primary Stimulation by Dendritic Cells Induces Antiviral Proliferative and Cytotoxic T Cell Responses In Vitro," <u>J. Exp. Med.</u>, 169:1255-1264, Apr. 1989.

Macatonia, et al., "Localization of Antigen on Lymph Node Dendritic Cells after Exposure to the Contact Sensitizer Fluorescein Isothiocyanate," <u>J. Exp. Med.</u>, 166:1654-1667, Dec. 1987.

Mason, D.W. et al.; "The Rat Mixed Lymphocyte Reaction: Roles Of A Dendritic Cell In Intestinal Lymph and T-Cell Subsets Defined By Monoclonal Antibodies," lmmunology, Sep. 1981, vol. 44, pp. 75-87.

McWilliam, et al., "Rapid Dendritic Cell Recruitment is a Hallmark of the Acute Imflammatory Response at Mucosal Surfaces," <u>J. Exp. Med.</u>, 179:1331-1336, Apr. 1994.

Metcalf, D., "The Molecular Control of Blood Cells," <u>Harvard Univ. Press, Cambridge, MA,</u> 1988.

Metcalf, D., "The Molecular Control of Cell Division Differentiation Commitment and Maturation in Haemopoietic Cells," Nature, 339:27-30 1989.

Metcalf, D., "Control of Granulocytes and Macrophages: Molecular, Cellular and Clinical Aspects," <u>Science</u>, 254:529-533 1991.

Mohamadzadeh, et al. "Functional and Morphological Characterization of 4F7+ Spleen Accessory Dendritic Cells," <u>Inter. Immun.</u>, 5/6:615-624.

Muster, et al., "An Influenza A Virus Containing Influenza B Virus 5' and 3' Noncoding Regions on the Neuraminidase Gene is Attenuated In Mice," <u>PNAS</u>, 88:5177-5181, Jun. 1991.

O'Doherty, et al., "Human Blood Contains Two Subsets of Dendritic Cells, One Immunologically Mature and the other Immature," Immunology, 82:487-493 1994.

O'Doherty, et al., "Dendritic Cell Freshly Isolated from Human Blood Express CD4 and Mature into Typical Immunostimulatory Dendritic Cell after Culture in Monocyte-conditioned Medium," <u>J. Exp. Med.</u>, 178:1067-1078, Sep. 1993.

Paglia et al, "Immortalized Dendritic Cell Line Fully Competent in Antigen Presentation Initiates Primary T Cell Responsed in Vivo," <u>J. Exp. Med.</u>, 1993 178: 1893-1901.

Peace, et al, "Lysis of Ras Oncogene-Transformed Cells by Specific Cytotoxic T Lymphocytes Elicited by Primary in Vitro Immunization with Mutated Ras Peptide," <u>J. Exp. Med.</u>, 179: 473-479, 1994.

Pettingell, et al, "Peripheral Blood Progenitor Cell Transportation in Lymphoma and Leukemia Using a Single Apheresis," <u>Blood</u>, Vol. 82, No. 12, December 15, 1993, pp. 3770-3777.

Pugh, et al., "Characterization of Nonlymphoid Cells Derived from Rat Peripheral Lymph," J. Exp. Med., 157:1758 1983.

Puré, et al., "Antigen Processing by Epidermal Langerhans Cells Correlates with the Level of Biosynthesis of Major Histocompatibility Complex Class II Molecules and Expression of Invariant Chain," <u>J. Exp. Med.</u>, 172:1459-1469 1990.

Reid, et al., "Identification of Hematopoietic Progenitors of Macrophases and Dendritic Langerhans Cells [DL-CFU] in Human Bone Marrow and Peripheral Blood," Blood, 76:1139-1149 1990.

Ria, et al, "Immunological Activity of Covalently Linked T-Cell Epitopes," <u>Nature</u>, 343: 381-383, 1990.

Riddell, et al., "Restoration of Viral Immunity of Immunodeficient Humans by the Adaptive Transfer of T Cell Clones," <u>Science</u>, 257:238-241, Jul. 1992.

Romani, et al, "Proliferating Dendritic Cell Progenitors in Human Blood," <u>J. Exp. Med.</u>, 180: 83-93 (1994).

Romani, et al., "Cultured Human Langerhans Cells Resemble Lymphoid Dendritic Cells in Phenotype and Function," <u>J. Invest. Dermatol.</u>, 93/5:600-609, Nov. 1989.

Romani, et al., "Presentation of Exogenous Protein Antigens by Dendritic Cells to T Cell Clones: Intact Protein is Presented Best by Immature, Epidermal Langerhans Cells," <u>J. Exp. Med.</u>, 169:1169-1178, 1989.

Sallusto, et al., "Efficient Presentation of Soluble Antigen By Cultured Human Dendritic Cells is Maintained By Granulocyte/Macrophage Colony-Stimulating Factor Plus Interleukin 4 and Downregulated By Tumor Necrois Factor-α," <u>J. Exp. Med.</u>, 179: 1109-1118 (Apr. 1994).

Santiago-Schwarz, et al., "TNF in Combination with GM-SF Enhances the Differentiation of Neonatal Cord Blood Stem Cells into Dendritic Cells and Macrophages," J. Leukocyte Biol., 52:274-281, 1992.

Sornasse, et al, "Loading of Dendritic Cells with Antigen in Vitro or in Vivo by Immunotargeting can Replace the Need for Adjuvant," <u>Adv. Exp. Med. Biol.</u>, 329:299-303, 1993.

Sprecher, et al., "Role of Langerhans Cells and other Dendritic Cells in Viral Diseases," <u>Arch Virol</u>, 132:1-28 1993.

Steinman, "Dendritic Cells: Clinical Aspects, 28th Forum of Immunology," Rockefeller Univ. and Irvington Inst. for Med. Res., pp. 911-924.

Steinman, et al., "Identification of a Novel Cell Type in Peripheral Lymphoid Organs of Mice. III," <u>J. Exp. Med.</u>, 139:1431 1974.

Stites et al, Basic and Clinical Immunology, Seventh Ed., Appelton & Lange, Norwalk, CT, pp. 21-22, 37, 97, 1991.

Teunissen, "Human Epidermal Langerhans Cells Undergo Profound Morphologic and Phenotypical Changes During In Vitro Culture," <u>J. Invest. Dermatol.</u>, 94:166-173 1990.

Thomas, et al. "Isolation and Characterization of Human Peripheral Blood Dendritic Cells," <u>J. Immunol.</u>, 150/3:821-834, Feb. 1993.

Thomas, et al., "Rheumatoid Synovium is Enriched in Mature Antigen-Presenting Dendritic Cells," <u>J. Immunol.</u>, 152:2613-2623 1993.

Troppmair, et al., "Interferons (IFNS) and Tumor Necrosis Factors (TNFS) in T Cell-Mediated Immune Responses Against Alloantigens. I. Influence On the Activation of Resting and Antigen-Primed T Cells," lmmunobiology, Vol. 176, pp. 236-254, 1988.

Wang, et al., "Epidermal Langerhans Cells from Normal Human Skin Bind Monomeric IgE via Fc Σ RI," <u>J. Exp. Med.</u>, 175:1353, May 1992.

Williams, et al., "Isolation and Function of Human Dendritic Cells," <u>International</u> Review of Cytology, 153:41-103 1994.

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Wraith, et al., "Influenza Virus-Specific Cytotoxic T-Cell Recognition: Stimulation Nucleoprotein-Specific Clones with Intact Antigen," lmmunology, 59:173-180 1986.

Wysocka, et al., "Identification of Overlapping Class I and Class II H-2^d Restricted T Cell Determinants of Influenza Virus N1 Neuraminidase That Require Infectious Virus for Presentation," <u>Virology</u>, 201:86-94, May 1994.

Young, et al., "Accessory Cell Requirements for the Mixed-Leukocyte Reaction and Polyclonal Mitogens, As Studied with a New Technique for Enriching Blood Dendritic Cells," Cell Immunol., 111:167-182 1988.

Young, et al., "Dendritic Cells Stimulate Primary Human Cytolytic Lymphocyte Responses in the Absence of CD4 Helper T Cells," <u>J. Exp. Med.</u>, 171:1315-1332, Apr. 1990.

Zvaifler, et al., "Identification of Immunostimulatory Dendritic Cells in the Synovial Effusions of Patients with Rheumatoid Arthritis," <u>J. Clin. Invest.</u>, 76:789-800, Aug. 1985.